

Serial No.: 10/027,134
Group Art Unit: 3739
Examiner: A. Roane
Atty. Docket No.: 102863-17

REMARKS

The present Office Action addresses and rejects claims 1-4, 6-13, 15, and 16. Applicants respectfully request reconsideration of the present application in view of the following remarks.

Rejections Pursuant to 35 U.S.C. §103

A. Yamanashi, Dorn, and Tetzlaff

The Examiner rejects independent claims 1 and 13 pursuant to 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 5,964,759 of Yamanashi et al., U.S. Patent No. 6,334,860 of Dorn, and U.S. Patent No. 6,277,117 of Tetzlaff et al. The Examiner argues that Yamanashi discloses the claimed invention, except for first and second members that are pivotally connected, and substantially circular conductive elements extending along the length of the first and second members. Thus, the Examiner relies on Dorn to teach a pivot connection and Tetzlaff to teach "curved forcep jaws," arguing that it would have been obvious to modify the device of Yamanashi in view of Dorn and Tetzlaff to arrive at the claimed invention. Applicants respectfully disagree.

The Examiner has failed to establish a prima facie case of obviousness for several reasons. At the outset, the combination of references does not teach the claimed invention. The Examiner has further failed to identify the motivation necessary to combine the references, and rather is improperly relying on hindsight to pick and choose among isolated features in the prior art to piece together the claimed invention. The Examiner has also overlooked that fact that the references represent non-analogous art that cannot be relied on to render the claimed invention obvious.

(1) The Combination Of References Does Not Teach The Claimed Invention.

As noted above, the Examiner relies on Yamanashi to teach the claimed invention, except for a pivot connection between the first and second members, and substantially circular conductive elements extending along the length of the first and second members. The Examiner relies on Dorn to teach a pivot connection, however Dorn is merely cumulative and does not contribute to the teachings of Yamanashi. As shown in FIG. 3, Yamanashi already discloses a device having first and second members that are pivotally coupled to one another. The laparoscopic forceps have a pivot connection formed at the distal tip portion of each blade member to allow the distal tips (38, 40) to

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pivot with respect to one another. Dorn likewise teaches a cutting or coagulating tool having first and second members that are pivotally connected. The pivot connection is formed adjacent to the distal tips to allow the tips to pivot with respect to one another to grasp tissue therebetween. Dorn therefore does not contribute anything to the teachings of Yamanashi, but rather is merely cumulative. Accordingly, a person having ordinary skill in the art would not be motivated to modify the device of Yamanashi to include the pivot connection taught by Dorn.

Even if Yamanashi and Dorn could be combined, neither reference teaches or even suggests substantially circular tissue-contacting conductive elements extending along the length of the first and second members. As shown in Figure 2 of Yamanashi, the distal tips do not include tissue-contacting conductive elements extending therealong, much less conductive elements having a substantially circular shape. Rather, the distal tips *are* the tissue-contacting conductive elements. Dorn, like Yamanashi, also fails to teach first and second members having a substantially circular conductive element extending along the length thereof, as required by independent claims 1 and 13. As shown in Figure 2, each jaw has a substantially planar surface with "conductive elements 36, 38 having a *plate-like form . . .*" (Col. 5, line 41, emphasis added.) Tetzlaff does not remedy the deficiencies of Yamanashi and/or Dorn.

The Examiner asserts that Tetzlaff teaches "curved forceps jaws." Independent claims 1 and 13, however, do not require "curved forceps jaws," but rather require first and second members having substantially circular conductive elements extending along the length thereof. Tetzlaff, like Yamanashi and Dorn, does not teach or suggest any type of substantially circular conductive element extending along a length of the jaws. Rather, as shown best in FIG. 3, the jaws are substantially planar, and the conductive elements are in the form of electrodes (120, 121) that disposed on the distal-most tips thereof. The electrodes do not have a substantially circular shape, and they do not extend along the length of the jaws. Accordingly, Tetzlaff fails to remedy the deficiencies of Yamanashi and Dorn, and therefore claims 1 and 13 distinguish over Yamanashi, Dorn, and Tetzlaff, taken alone or combined.

- (2) *The Examiner has further failed to identify the motivation necessary to combine the references.*

The Examiner has also failed to apply the legal requirement that the prior art be shown to

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provide sufficient motivation to one of ordinary skill in the art to combine the references. In combining references to support an obviousness rejection, an examiner may not simply pick and choose elements from different references, but must identify a teaching or motivation to combine the elements. The teaching or motivation must come from the references, and it cannot be derived from Applicant's teachings.

In the pending Office Action, the Examiner argues that a person having ordinary skill in the art would have been motivated to modify Yamanashi in view of Tetzlaff to include curved coagulating tissue grasping surfaces "to provide hemostasis along a desired non-linear lesion." The Examiner's argument is flawed for at least two reasons. First, as previously noted, Tetzlaff does not teach non-conductive elements extending along the surface, but rather the device includes electrodes disposed on the distal-most tip of the device. Tetzlaff thus cannot be used to "provide hemostasis along a desired non-linear lesion." Accordingly, the Examiner's reliance on the advantages of using curved jaws, as disclosed by Tetzlaff, is misplaced. Second, Yamanashi already provides non-linear jaws having electrodes for use in providing hemostasis, i.e., in coagulating tissue. Figure 2 illustrates an embodiment in which the jaws include a bend formed therein, and the distal-most tip of each jaw is conductive to coagulate/cut tissue. Accordingly, Tetzlaff is merely cumulative and does not provide the necessary motivation to modify Yamanashi.

The Examiner's obviousness rejection can only be the product of impermissible hindsight. An Examiner may only establish a prima facie case of obviousness when "the teachings from the prior art itself would appear to have suggested the claimed subject matter to a person of ordinary skill in the art." *In re Bell*, 991 F.2d 781, 783 (Fed. Cir. 1993). In asserting that the prior art "suggested" the claimed subject matter, however, an Examiner must realize that "the mere fact that the prior art may be modified in the manner proposed by the Examiner neither makes the modification prima facie obvious nor obvious unless the prior art suggested the desirability of the modification." *In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992). "[A] rejection cannot be predicated on the mere identification . . . of individual components of claimed limitations. Rather, particular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed." *In re Werner Kotzab*, 217 F.3d 1365, 1371 (Fed. Cir. 2000). Moreover, the Examiner may not "use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed

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invention is rendered obvious." *Id.* The Federal Circuit has further stated that "[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention." *Id.*

Applicants were motivated by problems discovered, and which were not recognized by Yamanashi, Dorn, or Tetzlaff, to develop a unique configuration for an ablation instrument. The Examiner's picking and choosing of features out of context from three different references in an attempt to construct a *prima facie* obviousness rejection boils down to an impermissible hindsight reconstruction of Applicant's invention. Applicant's claimed invention is patentable over the combination of Yamanashi, Dorn, or Tetzlaff.

Accordingly, independent claims 1 and 13 distinguish over Yamanashi, Dorn, and Tetzlaff, taken alone or combined, and therefore represent allowable subject matter. The Examiner rejects several of the dependent claims as being obvious over Yamanashi, Dorn, and Tetzlaff, as well as various other references, however these claims are also allowable at least because they depend from an allowable base claim.

(3) *The References Are Non-Analogous Art.*

The Examiner has also overlooked the fact that the cited references represent non-analogous art that cannot be relied on to formulate an obviousness rejection over the pending claims. In order to rely on a reference in analyzing the obviousness of the subject matter at issue, the reference must be analogous prior art. A reference is "analogous" if (1) the reference is within the field of the inventor's endeavor, and if it is not then (2) the reference must be reasonably pertinent to the particular problem with which the inventor was involved. Yamanashi, Dorn, and Tetzlaff are not within the field of the inventor's endeavor, and they are certainly not reasonably pertinent to the problem to be solved.

Yamanashi, Dorn, and Tetzlaff are directed to tools used to *coagulate* or *cut* tissue. The present invention, on the other hand, is directed to an ablation device for use in *ablating* tissue. No person having ordinary skill in the art would combine various references directed to cutting or coagulating tools to arrive at an ablation tool. These are distinct medical devices that are used for

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very different purposes. Accordingly, the cutting and coagulating tools disclosed by Yamanashi, Dorn, and Tetzlaff are not within the field of applicant's endeavor, namely ablation.

Yamanashi, Dorn, and Tetzlaff are also not reasonably pertinent to the problem being solved by the applicants of the claimed invention. The present invention is directed toward an ablation instrument that can be used to form an ablative lesion uniformly through an entire thickness of tissue, e.g., the myocardial wall. The tissue-piercing tip of one of the members allows the members to grasp tissue therebetween to form a uniform lesion. Yamanashi, Dorn, and Tetzlaff, on the other hand, are specifically directed toward improved cutting and coagulating tools. In particular, Yamanashi is directed to a monopolar electroconvergent cautery system that does not require the use of a solenoid coil or a grounding component. Dorn is directed to a means for electrically insulating a miniaturized configuration of the jaw parts of a bipolar medical instrument. Tetzlaff is directed to forceps having a removable and disposed electrode assembly that mates thereto. None of these references are pertinent to forming a uniform lesion through an entire thickness of tissue, and in fact none of the references even teach or suggest any type of device that is capable of forming an ablative lesion. Accordingly, Yamanashi, Dorn, and Tetzlaff are also not pertinent to the problem being solved by the present invention, and therefore represent non-analogous art that cannot be relied on to reject the claimed invention.

B. Fozard, Mehl, and Grisoni

The Examiner also rejects independent claims 1 and 13 as being obvious over U.S. Patent No. 2,888,927 of Fozard in view of U.S. Patent No. 8,546,252 of Mehl, Sr. and further in view of U.S. Patent No. D452,936 of Grisoni. The Examiner argues that Fozard teaches the claimed invention, except for a second electrically conductive element on the second member, and first and second tissue contacting conductive elements that are substantially circular in shape and extend along a length of the first and second members. The Examiner therefore argues that it would have been obvious to modify Fozard to include a second conductive element, as taught by Mehl, and to include curved jaws, as taught by Grisoni. Applicants disagree.

Again, the Examiner has failed to establish a prima facie case of obviousness. Namely, the combination of references does not teach the claimed invention. The references also represent non-analogous art that cannot be relied on to reject the claimed invention.

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(1) *The Combination Of References Does Not Teach The Claimed Invention.*

While Applicants do not agree that it would have been obvious to modify Fozard in view of Mehl and Grisoni, even if the references could be combined the combination does not teach the claimed invention. None of the references teach or even suggest first and second members having substantially circular conductive elements extending along a length thereof, as required by independent claims 1 and 13. Fozard and Mehl each disclose precision tweezers for removing hair. Only a distal tip of each tweezer is conductive, and the conductive member is not substantially circular, nor does it extend along a length of the members. Grisoni does not remedy the deficiencies of Fozard and Mehl, as Grisoni is merely directed to the ornamental design for a pair of tweezers having a curved configuration. The tweezers do not include any type of conductive element, much less one that extends along a length of first and second members and has a substantially circular shape.

Accordingly, independent claims 1 and 13 distinguish over Fozard, Mehl, and Grisoni, taken alone or combined. The Examiner rejects dependent claim 11 as being obvious over Fozard, Mehl, and Grisoni, however this claim is also allowable at least because it depends from an allowable base claim.

(3) *The References Are Non-Analogous Art.*

For similar reasons discussed above, Fozard, Mehl, and Grisoni are non-analogous art and would not be combined to arrive at the claimed invention. Fozard, Mehl, and Grisoni are not within the field of the inventor's endeavor, and they are not reasonably pertinent to the particular problem with which the inventor was involved. Fozard, Mehl, and Grisoni are directed to precision tweezers used to **grasp and remove hair**. The present invention, on the other hand, is directed to an ablation device for use in forming an **ablative lesion**. Tweezers used to grasp hair are clearly not within the field of applicants endeavor, and no person having ordinary skill in the art would combine various references directed to tweezers to arrive at an ablation tool. The tweezers disclosed by Fozard, Mehl, and Grisoni are also clearly not reasonably pertinent to the problem being solved by the applicants of the claimed invention, as none of the references are directed toward solving the problem of forming an ablative lesion uniformly through an entire thickness of tissue. Accordingly, Fozard, Mehl, and Grisoni are non-analogous art that cannot be relied on to reject the claimed invention.

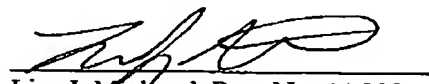
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Conclusion

In view of the amendments and remarks above, Applicants submit that all pending claims are in condition for allowance and allowance thereof is respectfully requested. Applicants encourage the Examiner to telephone the undersigned in the event that such communication might expedite prosecution of this matter.

Respectfully submitted,

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